

## **REMARKS**

Reconsideration of this application is requested in view of the amendments to the claims and the remarks presented herein.

The claims in the application are claims 30 to 46, all other claims having been cancelled.

With respect to the Examiner's restriction requirement, Applicants are submitting herewith a Petition to the Commissioner with respect to the improper thereof.

With respect to the Examiner's rejection under 35 USC 101, it is believed that the rejection has been obviated by the present claims which use the term "isolated" and therefore, withdrawal of this ground of rejection is requested.

Claims 1 to 10, 12 to 16, 27 and 29 were rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement since in the Examiner's opinion, the specification broadly describes isolated polynucleotides comprising a nucleotide sequence encoding the polypeptide having the same function and having and amino acid sequence homologous with SEQ ID No: 12 and deems the function of the protein whose SEQ ID No: 12 is not taught nor described.

Applicants respectfully traverse this ground of rejection since it is deemed that the present claims are clearly enabled by the specification. There is a strong presumption that an adequate written description of the claimed invention is present. In the decision of *In re Wertheim*, 191 USPQ 90, 97, it has been clearly stated that “The PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.”

Applicants believe that the Examiner has failed to give real evidence or reasons why one skilled in the art would not recognize from the disclosure a description of the invention defined by the present claims.

According to the guidelines for the examination of patent applications under 35 USC 112, “The analysis of whether the specification complies with the written description requirement calls for the Examiner to compare the scope of the claim with the scope of the description to determine whether Applicant has demonstrated the possession of the claimed invention. Such a review is conducted from the standpoint of one skilled in the art at the time the application was filed (See *Wang Labs. v. Toshiba Corp.*, 26 USPQ 2<sup>nd</sup> 1767 – 1774) and should include a determination of the field of the invention as the level and skill and knowledge in the art.” The Examiner has failed to comply with the guidelines since he has not determined the level of skill and knowledge of one skilled in the art at the time the application was filed. The Examiner cited, for example, art dated 1976, 1988, 1990 and 1991. However, the present application was filed on June 1999. During that period, the knowledge in the biotech field had drastically increased.

In *The Regents of the University of California v. Eli Lilly*, the Court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules usually defined by a nucleotide sequence falling within the scope of the claimed genus. As noted above, the analysis concerning the written description has to be conducted from the standpoint of one skilled in the art at the time the application was filed. The two patents that were involved in the said decision were filed on June 8, 1982 and June 28, 1983.

In contrast thereto, the present application has been filed on June 9, 1997, that is to say 17 years after the patents in suit in *The Regents of the University of California v. Eli Lilly*. During that period of time, the knowledge in the biotech field has dramatically increased and therefore, the finding of *The Regents of the University of California v. Eli Lilly* cannot be directly transposed to the present application. Compliance with the written description requirement is a question of fact and must be resolved on a case-by-case basis. Applicants believe that the description clearly allows one skilled in the art to recognize that the Applicant invented what is presently claimed. The claims now are not broadly written in view of the knowledge of one skilled in the art at the time the application was filed. According to the guidelines, "The disclosure of a single disclosed species may provide an adequate written description of a genus when the species

disclosed is representative of a genus.” Therefore, it is believed that the present claims clearly comply with 35 USC 112, first paragraph, and withdrawal of this ground of rejection is requested.

Claims 17 and 29 were rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement since, in the Examiner’s opinion, the specification lacked complete deposit information for the deposit of plasmid I-2212 since it was not clear that the deposit was made in accordance with the Budapest Treaty.

Applicants’ attorney confirms that the plasmid of claim 17, now claim 44, was made in accordance with the Budapest Treaty. Applicants are submitting herewith copies of the corresponding receipts therefore with respect to the deposits under Nos. I-2211, I-2212, I-2213, I-2214, I-2215, I-2216 and I-2217. All deposits were made in accordance with the Budapest Treaty. Therefore, withdrawal of this ground of rejection is requested.

Claims 1 to 10, 12 to 17, 27 and 29 were rejected under 35 USC 112, second paragraph, as being indefinite. The Examiner was of the opinion that the specification did not describe the “function” of the protein polypeptide and as such the metes and bounds are not met. The Examiner was of the opinion that the claims were indefinite as well.


Applicants respectfully traverse these grounds of rejection since these rejections are not applicable to the claims as presented in claims 30 to 46. Therefore, withdrawal of this ground of rejection is requested.

Claims 1 to 3, 5, 7 to 10 and 27 were rejected as being anticipated by the Database GenEMBL database, Accession number Z71536, Y13139, Sen-Gupta et al. Claims 1 to 3, 5, 7 to 10 and 27 were rejected under 35 USC 102 as being anticipated by the Lin et al, PNAS, 92(9):3784-3788, 1995, nucleic acid Database GenEMBL database. Accession number L35270.

Applicants respectfully traverse these grounds of rejection since none of the prior art cited by the Examiner discloses polynucleotides or polypeptides according to claims 20 to 35. Sen-Gupta et al and Lin et al present a polynucleotide encoding a polynucleotide from *S. Cerevisiae* which is far removed from SEQ ID No: 12 (28.89% of homology on a portion of SEQ ID No: 12 according to the BLAST program). This is far removed from the polypeptides and polynucleotides as currently claimed in the application and therefore, the references do not anticipate or render obvious Applicants' polynucleotides and polypeptides as currently claimed and withdrawal of this ground of rejection is requested.

It is believed that the present claims fully comply with 35 USC 112, second paragraph and the Examiner's suggestions have been adopted where appropriate. Therefore, the amended claims are believed to comply with 35 USC 112 and withdrawal of this ground of rejection is requested.

Respectfully submitted,  
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Enclosures